

**REMARKS**

The above-identified application has been reviewed in light of the Final Office Action mailed April 12, 2010 and the Advisory Action mailed on June 10, 2010, and in view of the Request for Continued Examination submitted herewith. Claims 11-12, 16-20, 28, 31-32, 39-40, 42-43 and 44-49 are currently pending with claims 11, 28, 39 and 44 being in independent form. Claims 11, 16-19, 28, 39 and 44-46 have been currently amended. Claims 1-10, 13-15, 21-27, 29-30, 33-38 and 41 have been canceled with Claims 15 and 33 having been currently canceled herein. New dependent Claims 47-49 have been added herein. It is respectfully submitted that the claims pending in the application are fully supported by the specification, introduce no new matter, and are patentable over the prior art. In view of the amendments and the remarks to follow, early and favorable reconsideration and allowance of this application is respectfully requested.

Applicants would like to thank Examiner Houston for the courtesy extended to the Applicants' attorney during the telephone interview conducted on July 22, 2010. In the interview, Examiner Houston and Applicants' attorney discussed that independent Claim 11, as amended herein, may be allowable over the cited art of record with the Examiner reserving the right to review the claim amendments in greater detail in view of the art of record.

In the Final Office Action, Claims 11, 12, 15-19, 28, 31-33 and 44-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,176,127 to Dormia (hereinafter referred to as "Dormia") in view of U.S. Patent No. 6,332,877 to Michels

(hereinafter referred to as “Michels”). Applicants respectfully submit that independent Claims 11, 28 and 44 as amended, are allowable over Dormia in view of Michels.

According to § 2143.03 of the MPEP, in order “to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.”

Independent Claim 11 recites an orifice introducer device comprising, *inter alia*, “a tubular insertion device positioned within the lumen of the tubular member; a distal portion having a proximal end detachably connected to the tubular member...the tubular insertion device configured to detach the distal portion from the tubular member, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts from a radially outward position to a radially inward position such that the distal portion has an outer diameter smaller than an inside diameter of the tubular insertion device.” (Emphasis added).

In an embodiment of the present application, the proximal end 310a of the distal portion 310 contracts sufficiently such that the outer diameter of the distal portion 310 is smaller than the inside diameter of the tubular insertion device 330. In this manner, the distal portion 310 is proximally withdrawn through the tubular insertion device 330 while leaving the tubular insertion device 330 in place within the tubular member 300. In this embodiment, both the tubular member 300 and the tubular insertion device 330 remain in position within the orifice, and a surgical device thereafter is inserted into the proximal end 330a of the tubular insertion device 330 and advanced distally therethrough. (See Paragraph [0041] of the present application).

In contrast, Dormia discloses, as shown in Figures 3 and 5, reproduced below, a spreadable head 9, a rod-shaped slide 10, and a jacket 1 of an endoscope. When the rod-shaped slide 10 is inserted within the spreadable head 9, the segments 12 are spread outwards until the outer circumferential edge 15 covers the underlying edge 6 of the jacket 1 of the endoscope. (See Dormia at col. 4, lines 3-32). However, nowhere does Dormia disclose the distal portion contracting so as to have a diameter smaller than a diameter of the tubular insertion device, as substantially called for in Claim 11.

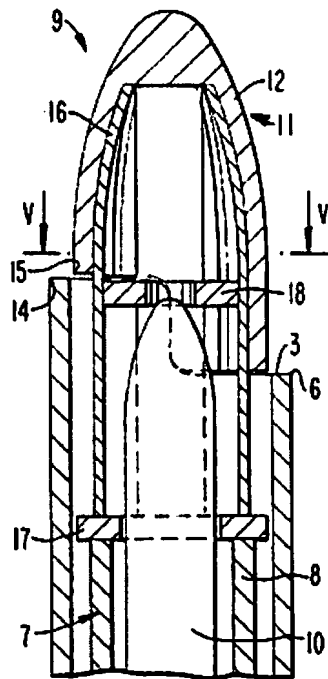


FIG. 3

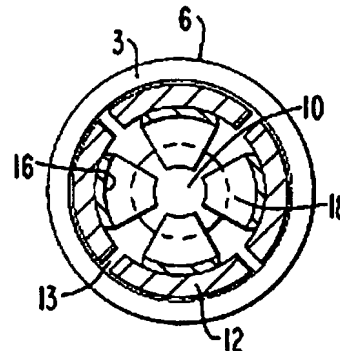
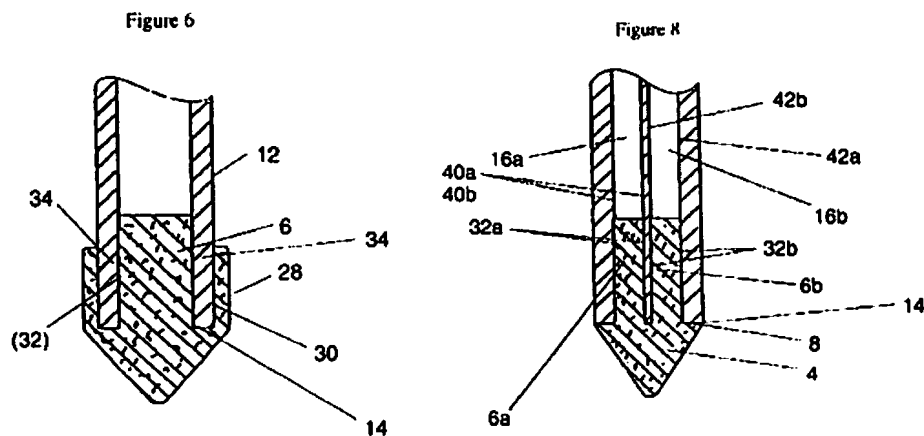


FIG. 5

Michels discloses an ostomy tube including a body portion 6, as shown in Figure 6, reproduced below, that is designed to fit within the lumen of the tube 12, while the outer cylindrical skirt 28 fits over and surrounds the periphery of the tube 12. (See Michels at col. 6, lines 16-21). Michels further discloses body portions 6a and 6b, as shown in Figure 8,

reproduced below, that are designed to fit within the lumen of the tube 14, while the while the base 8 of the cap and head portion 4 is flush with the tip of the tube 14. (See Michels at col. 6, lines 33-37). However, nowhere does Michels disclose the distal portion contracting so as to have a diameter smaller than a diameter of the tubular insertion device, as substantially called for in Claim 11.

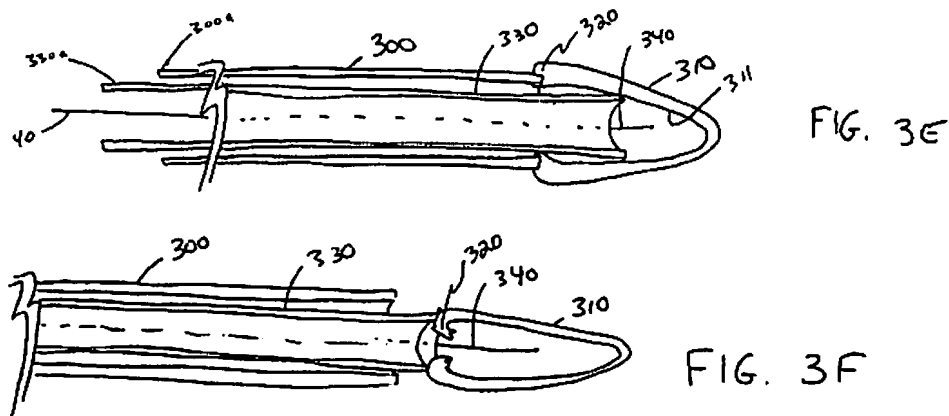


In view of the foregoing, Applicants respectfully submit that Dormia and Michels, either alone or in any proper combination with each other, do not teach or suggest that “the distal portion contracting so as to have a diameter smaller than a diameter of the tubular insertion device,” as recited in Claim 11.

Independent claim 28 recites a method for using an orifice introducer device comprising, *inter alia*, the step of: “selectively detaching the distal portion from the tubular member by inserting a tubular insertion device through the tubular member to distally move the distal

portion; the distal portion contracting so as to have a diameter smaller than a diameter of the tubular member.” (Emphasis added)

In an embodiment of the present application, as shown in Figure 3F, reproduced below, forward longitudinal movement of a tubular insertion device 330 urges a distal portion 310 to move forward, which causes a proximal end of the distal portion 310 to detach from a distal end of a tubular member 300. In this manner, when the distal portion 310 detaches from the tubular member 300, the distal portion 310 contracts radially inwardly. (See Specification at paragraphs [0039] - [0040] and Figures 3E-3F).



In contrast, when the mandrel or rod-shaped slide 10 of Dormia, which the Examiner characterizes as the tubular insertion device 330, (See Final Office Action at page 3, paragraph 6) is moved in a forward longitudinal movement, the radial position of the spreadable head 9 of Dormia is not effected. In fact, the forward longitudinal movement of the rod-shaped slide 10 has the opposite effect in that it causes radially outward expansion of the spreadable head 9. (See Dormia at col. 3, lines 58-63 and Figure 6)

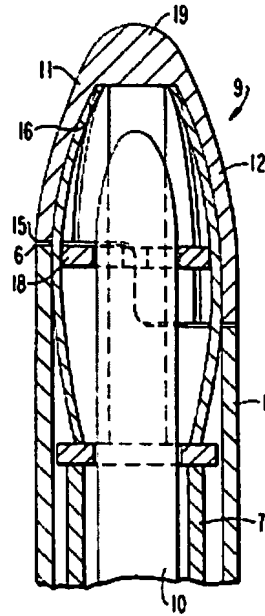
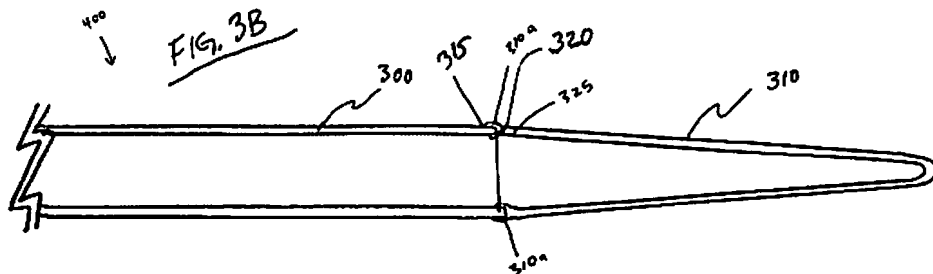


FIG. 6

In view of the foregoing, Applicants respectfully submit that Dormia and Michels, either alone or in any proper combination with each other, do not teach or suggest that “selectively detaching the distal portion from the tubular member by inserting a tubular insertion device through the tubular member to distally move the distal portion; the distal portion contracting so as to have a diameter smaller than a diameter of the tubular member,” as recited in Claim 28.

Independent claim 44 recites an orifice introducer device comprising, *inter alia*, a tubular member having a lumen and a distal end and “a distal portion having a proximal end detachably connectable to the tubular member, the proximal end having an annular groove configured to receive the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction.”

In an embodiment of the present application, as shown in Figure 3E, reproduced below, the distal portion 310 is stretched around a distal end 315 of the tubular member 300 such that the distal portion 310 is maintained in a radially expanded position by being detachably connected to the tubular member 300. (See Specification at paragraph [0034] and Figure 3B).



In contrast, the spreadable head 9 of Dormia is maintained in its radially expanded position only by engagement by a third component, i.e., the rod-shaped slide 10 pressing radially outwardly against it. More specifically, Dormia discloses the following at col. 4, lines 30-41:

[T]he radial outward displacement of the segments 12 is achieved using the rod-shaped slide 10, which for this purpose has a pointed end and exhibits an external diameter which, after carrying out the spreading stroke, as illustrated in FIGS. 5 and 6, causes an essentially radially outward directed spreading of the segments 12 of the head 9. In this position, the outer circumferential edge 6 of the tubular jacket 1 of the endoscope does not constitute a sharp edge, which could lead to injuries, since the edge 6 is covered by the external circumference of the mandrel head 9 of essentially equal diameter. (Emphasis added)

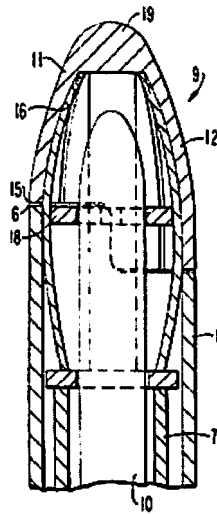


FIG. 6

Nowhere does Dormia disclose, teach or suggest that the spreadable head 9 is maintained in its radially expanded position by its engagement with the tubular member 1.

In view of the foregoing, Applicants respectfully submit that Dormia and Michels, either alone or in any proper combination with each other, do not teach or suggest that “a distal portion having a proximal end detachably connectable to the tubular member, the proximal end having an annular groove configured to receive the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction” as recited in Claim 44.

Since Claims 12 and 16-19 depend, directly or indirectly, from Claim 11 and contain all the features of Claim 11, Claims 31-32 depend, directly or indirectly, from Claim 28, and Claims 45-46 depend, directly or indirectly, from Claim 44, Applicants respectfully submit that for at least the reasons stated above for Claim 11, 28 and 44, Claims 12, 16-19, 31-32 and 45-46 are



also allowable under 35 U.S.C. § 103(a) over Dormia in view of Michels. Claims 15 and 33 have been canceled, without prejudice. Accordingly, these rejections have been rendered moot.

In the Final Office Action, Claims 20 and 39-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dormia in view of Michels, as applied to Claim 11, and further in view of U.S. Patent No. 6,042,538 to Puskas (hereinafter referred to as "Puskas"). Applicants respectfully submit that independent Claim 39 is allowable over Dormia in view of Michels, as applied to Claim 11, and further in view of Puskas.

Independent claim 39 recites a device comprising, *inter alia*, a tubular member, "a second member being arranged internally within the tubular member and being configured to move longitudinally relative to the tubular member" and "wherein a recovery device is configured to withdraw the distal portion through the lumen of the tubular member after the second member has been withdrawn from the tubular member."

In an embodiment of the present application, as shown in Figure 3G, reproduced below, the distal portion 310 is simply urged or pushed by the tubular insertion device 330 in a longitudinal manner. Thus, the tubular insertion device 330 can be separately retracted or left in place. (See Specification at paragraph [0038]-[0040] and Figure 3G).

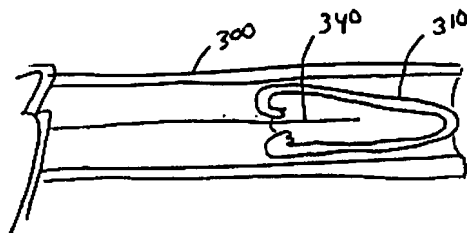


FIG. 3G

In contrast, the head 9 of Dormia is permanently attached to the mandrel 7. More specifically, the mandrel 7 of Dormia is designed as a tube 8 which supports, at its end, a mandrel head 9 which is designed such that it can be spread radially and is provided with a rod-shaped slide 10 during a spreading procedure. (See Dormia at col. 3, lines 58-63). Further, the spreadable head 9 of the mandrel 7 is made up of profiled head segments 12, which are obtained directly from strip-shaped, elastic components 16. (See Dormia at col. 5, lines 21-25).

Applicants respectfully submit that Dormia and Michels, either alone or in any proper combination with each other, do not teach or suggest “a second member being arranged internally within the tubular member and being configured to move longitudinally relative to the tubular member “ and “wherein a recovery device is configured to withdraw the distal portion through the lumen of the tubular member after the second member has been withdrawn from the tubular member,” as substantially recited in Claim 39.

Puskas does not cure the deficiencies of Dormia and Michels, nor is Puskas cited in the Final Office Action as curing the above-noted deficiencies of Dormia and Michels. Rather, Puskas is merely cited as disclosing inserting instruments into an endoscope that include retractors, staplers, suction devices, and electric devices. Since Puskas does not cure the deficiencies of Dormia and Michels, with respect to Claim 39, Applicant submits that the subject matter of Claim 39 is patentable over Dormia and Michels, as applied to Claim 11, and further in view of Puskas and that Claim 39 is in condition for allowance.

Since Claims 40 and 42-43 depend directly from Claim 39 and contain all the features of Claim 39, Applicants submit that Claims 40 and 42-43 are also allowable under 35 U.S.C. §

103(a) over Dormia in view of Michels, as applied to Claim 11, and further in view of Puskas. Furthermore, since Claim 20 directly depends from independent Claim 11 and contains all of the limitations thereof, Applicants respectfully submit that the subject matter of Claim 20 is patentable for at least the reasons that independent Claim 11 is patentable. Claim 41 has been canceled, without prejudice. Accordingly, this rejection has been rendered moot.

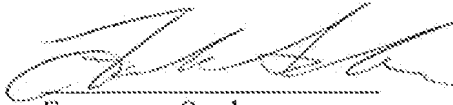
New dependent claims 47 and 48 are directed to the distal portion having a first expanded configuration and a second contracted configuration. New dependent claim 49 is directed to at least a portion of the recovery device engages an inner portion of the distal portion. Applicants submit that new claims 47-49 are patentably distinguishable over the cited art of record and are in condition for allowance.

Should the Examiner desire a telephonic interview to resolve any outstanding matters, the Examiner is sincerely invited to contact the undersigned at the number indicated below.

Application No. 10/632,271  
Reply to the Final Office Action dated April 12, 2010 and  
the Advisory Action mailed on June 10, 2010

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,



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